REMARKS

Claims 1-3, 5-7 and 13-125 are all the claims pending in the application.

Substitute specification

In the Office Action, the Examiner has objected to the drawings (paragraph 3) and has rejected Claims 25-125 under 35 U.S.C. §112, first paragraph. In order to overcome the objections and rejections, the applicants submit herewith a substitute specification.

The matter added to the specification as filed is disclosed in United States Patent 5,674,296 ("'296 patent), a copy of which is enclosed for the convenience of the Examiner. The specification as originally filed expressly incorporates by reference the '296 patent (page 3, lines 7-8). Accordingly, no question of new matter arises from the amendment of the specification to include additional disclosure from the '296 patent.

More specifically, the disclosure added to the specification is compared with the corresponding disclosure of the '296 patent, by reference to the paragraph numbers of the substitute specification and the columns and line numbers of the '296 patent, as follows:

SUBSTITUTE SPECIFICATION	**'296 PATENT DISCLOSURE**
Paragraph 10	Abstract
Paragraph 20	Fig. 1 (col. 3, lines 8-10)
Paragraph 21	Fig. 2 (col. 3, lines 10-13)
Paragraph 22	Fig. 3 (col. 3, lines 14-16)

Paragraph 23	Fig. 4 (col. 3, lines 17-18)
Paragraph 40	Figs. 1-4; col. 3, lines 8-18
Paragraph 41	col. 3, line 58-col. 4, line 1
Paragraph 42	col. 4, lines 6-17
Paragraph 43	col. 4, lines 17-30
Paragraph 44	col. 4, lines 31-52
Paragraph 45	col. 4, lines 6-17
Paragraph 46	col. 2, lines 31-33
Paragraph 48	col. 2, lines 31-33
Paragraph 49	col. 6, lines 16-38
Paragraph 50	col. 6, lines 40-46
Paragraph 51	col. 6, lines 47-56
Paragraph 52	col. 4, lines 6-18
Paragraph 53	col. 6, line 65-col. 7, line 2

ADDITIONAL DRAWINGS

Fig. 4	Fig. 1
Fig. 5	Fig. 2
Fig. 6	Fig. 3
Fig. 7	Fig. 4

ABSTRACT

Abstract col. 6, line 16 to col. 7, line 2

DISCLOSURE PRESENT IN ORIGINAL SPECIFICATION

In addition to disclosure incorporated by reference from the '296 patent, paragraph 37 of the substitute specification corresponds to page 5, lines 3-6 of the original specification.

Paragraph 38 added to the substitute specification corresponds to page 5, lines 7-18 of the original specification.

Paragraph 39 added to the substitute specification corresponds to page 6, lines 3-10 of the original specification.

Paragraph 40 added to the substitute specification corresponds to page 5, lines 7-14 of the original specification.

Paragraph 47 of the substitute specification describes features of the invention shown in Figs. 1-3 of the original specification and by Figs 4-6, and is supported by page 5, lines 7-14 of the original specification filed and by col. 3, line 58 to col. 4, line 1, and col 6, lines 57-62 of the '296 patent.

Paragraph 52 of the substitute specification is supported by col. 6, lines 56-62 of the '296 patent, and by the original specification, page 5, lines 7-18. Figure 2 discloses a

rotary form cutter 29 that has two distinct milling surfaces, an inner convex milling surface 42, surrounded by an outer concaval milling surface which terminates at peripheral edge 44 (Specification, ¶¶25-26), and thus shows a form cutter having at least one milling surface 42, 44 as stated in Paragraph 52.

Paragraph 31 of the substitute specification corresponds to page 7, lines 3-6 of the original specification, and is amended to further describe the reference numerals added to Fig. 2, which indicate the second upstanding wall 45 and the slot 46 through which the drive shaft 54 extends. These features of the invention are shown in original Fig. 2.

The substitute specification thus does not contain new matter. Entry and consideration of the substitute specification are respectfully requested.

Objections to the Drawings

In paragraph 3 of the Office Action, the Examiner has objected to the drawings under 37 CFR 1.83(a) stating that the drawings must show every feature of the invention specified in the claims. The Examiner requires that the predetermined shape of an endoprosthesis (claim 18), the "concaval-convex shape" of an endoprosthesis (claim 24), the "surface contour in one of the adjacent vertebral bodies" (claims 24, 41, 47, 67, 82, 97, 114, 119, 120, 121), the "slot" (claims 29, 72, 86, 103), the "width of the insert" (claims 41, 49), the milling surface is "parallel to a receiving surface" (claims 49, 85, 102), the "nucleus puposus" (claim 51), the steps of the method claims 62-66, and the

"two predetermined surface contours" (claims 77, 93, 110), be shown or the feature(s) canceled from the claim(s).

In response to the objection with respect to the predetermined shape of an endoprosthesis (claim 18), the "concaval-convex shape" of an endoprosthesis (claim 24), the "surface contour in one of the adjacent vertebral bodies" (claims 24, 41, 47, 67, 82, 97, 114, 119, 120, 121), the "width of the insert" (claims 41, 49), and the recitation that the milling surface is "parallel to a receiving surface" (claims 49, 85, 102), applicants have incorporated drawings from the '296 patent in the substitute specification which, taken in combination with original Figs. 1-3 clearly disclose these features of the claimed invention.

"Predetermined shape of an endoprosthesis"

With respect to Claim 18, an endoprosthesis 118 having a representative predetermined shape defined by outer convex contours 152, 154 in contact with the milled concaval vertebral end plate surfaces 212, 214, is shown in Fig. 6. (Specification, ¶42). The shape of the endoprosthesis 118 is shown in detail in Fig. 7. (Specification, ¶45).

"Concaval-convex shape of an endoprosthesis"

With respect to Claim 24, a representative rotary cutter profile having two milling surfaces which simultaneously form a concaval-convex shape in a vertebral end surface 112, 114, is shown in Fig. 2. The inner convex milling surface 42 of the form cutter 29

mills a corresponding concaval shape 212, 214 in the end plate of a vertebra 112, 114 that matches the outer convex shape 152, 154 of an endoprosthesis. (Specification, ¶¶ 49-53). The concaval milling surface which extends outwardly and upwardly about the perimeter to the edge 44 of form cutter 29 in Fig. 2 matches a concaval outer annular surface shape of an endoprosthesis. (Specification, ¶¶ 26-27).

"Surface contour in one of the adjacent vertebral bodies"

With respect to Claims 18, 24, 41, 47, 67, 82, 97, 114, 119, 120, and 121, an illustrative surface contour 152, 154 in an end plate of the vertebral bodies 112, 114 is milled by using a form cutter 29 according to the invention, which has a milling surface contour 42 matching the surface contour 152, 154 formed by milling the vertebral body, is now shown in Figs. 3-7.

"Slot"

In response to the objection with respect to the "slot" (Claims 29, 72, 86 and 103), applicants amend Figure 2 of the specification to include numerical references identifying the slot 46 configured through the upstanding wall 45 through which the drive shaft 54 is operatively coupled to the form cutter 29. (Specification, ¶31). The slot 46 shown in Fig. 2 extends through the surface of the upstanding wall adjacent 45 inside the housing 40 near its proximal end. The upstanding wall 45 has slot 46 through which the drive shaft 54 extends and through which the drive shaft 54 is operatively coupled to the form cutter 29. As shown in original Figure 2, the wall 45 is an integral part of the housing 40. No

question of new matter should arise, and entry of amended Fig. 2 is respectfully requested.

"Width of the insert"

With respect to the recitation of Claims 41 and 49 that the milling surface of the form cutter has a width selected to substantially match the overall width of the insert, this feature of the claimed invention is clearly shown by Figs. 2-3, in which the form cutter 29 has a cutting surface including convex portion 42 and an outer concave portion terminating at edge 44. (Specification, ¶¶ 26-27). The width of the form cutter milling surface is thus the diameter of the cutting surface terminating at peripheral edge 44, and is selected to mill a corresponding shape in a vertebral end plate, which has substantially the same overall width as a convex-concaval insert to be received between the milled end plates 152, 154 of adjacent vertebral bodies 112, 114 as shown in Figs. 4-6. As disclosed in the specification (¶52), a representative form cutter 29 having two milling surfaces 42, 44 is selected to create a predetermined surface contour in one of the adjacent vertebral bodies as the form cutter is moved by drive means 24, using one of a selection of predetermined form cutter sizes. The specification (¶53) further discloses that the concaval-convex elements 152, 154 of an insert are identical in shape to the milled surfaces 212, 214.

"Milling surface is "parallel to a receiving surface"

With respect to the recitation of Claims 49, 85 and 102 that the milling surface is configured to be "parallel to a receiving surface" that is formed in the vertebral body, applicants respectfully submit that this feature is shown by Figs. 1-3 as originally filed. When the rotary cutter 29 is driven in rotary motion by drive means 24, the movement of the rotating milling surfaces 42, 44, is in a plane that is generally parallel to a receiving surface in the end plates of a vertebral body 112, 114 as shown more particularly in Figs. 4-5. (Specification, ¶¶25-26, 50-53).

"Nucleus pulposus"

With respect to the recitation of Claim 51 that the width of the milling surface substantially matches the width of the nucleus pulposus of a disc space in which the milling surface is inserted, applicants submit that it would be clear to a person of ordinary skill in this art that the surface contour formed in the vertebral surface can be varied according to the width of the prosthesis as desired. The substitute specification (¶¶ 47-48) discloses that the present method may be used to form any predetermined shape in at least one of two adjacent vertebral bodies, to receive an endoprosthesis of any desired predetermined shape, and is not limited to the specific illustrative endoprostheses described in Figs. 4-7. However, in order to advance prosecution, Claim 51 has been cancelled without prejudice.

Steps of method claims

With respect to the steps of the method as claimed in Claims 62-66, it is respectfully submitted that the objection is overcome by the incorporation of Figs. 4-7 and disclosure of the '296 patent. The substitute specification discloses (¶47) that the present invention includes a method of milling at least one of two adjacent vertebral bodies to form concaval-convex surfaces in the patient's spine, using drill head 20 as illustrated in Figs. 1-3. The concaval surfaces mate with corresponding surfaces of an endoprosthesis such as those described in Figs. 4-7. When a suitable endoprosthesis is made and the patient is properly prepared, the damaged natural spinal disc or discs and vertebral body or bodies are removed and the adjacent spinal bone surfaces are milled or otherwise formed to provide concave surfaces 212, 214 to receive the confronting convex surfaces 152, 154 of the implant. (Specification, ¶50).

In the method of Claims 62-66, as described in the substitute specification (¶52) with reference to Figs. 1-7, the desired surfaces of predetermined shape are formed on the inferior and superior surfaces of the opposing vertebral bodies using a drill head according to the invention as shown in Figs. 1-3. The desired surface of predetermined shape 212, 214 is formed by contacting the inferior or superior surface of opposing vertebral bodies 112, 114, with a form cutter 29 having at least one milling surface 42, 44 selected to create a predetermined surface contour in one of the adjacent vertebral bodies

as the form cutter is moved by drive means 24, using one of a selection of predetermined form cutter sizes. (Specification, ¶¶25-27, 52).

As further described in the substitute specification (¶53), thereafter, the bone milling jig is removed and the concaval-convex elements 152, 154 identical in shape to the milled surfaces 212, 14 are inserted between the distracted milled vertebral bodies 112, 114.

It is respectfully submitted that the Examiner's objections are thus overcome by the disclosure of the substitute specification, which describes the steps of the method as claimed in Claims 62-66 with specific reference to Figs. 1-7.

"Two predetermined surface contours"

With respect to the recitation in Claims 79, 93 and 110 that the form cutter has two milling surface contours for simultaneously creating at least two predetermined surface contours on an end plate of one of the adjacent vertebral bodies, it is respectfully submitted that the representative form cutter 29 as shown in Figs. 1-3 and described in the specification (¶¶ 26-27) has two distinct milling surfaces. A first milling surface includes a convex milling surface 42, as illustrated in Fig. 2 as originally filed. (Specification, ¶26). A second milling surface is shown on form cutter 29 as an outwardly and upwardly extending concaval portion terminating at edge 44 about its perimeter. (Specification, ¶27). The two surfaces of the form cutter form a convex-concaval shape in the surface of a vertebra, and it is thus clear that the form cutter 29

illustrated in Fig. 2 has two milling surface contours which simultaneously create two predetermined surface contours on an end plate of one of the adjacent vertebral bodies. (Specification, ¶¶26, 29)

For these reasons, applicants respectfully submit that each feature of the claimed invention is disclosed by the drawings of the substitute specification. Withdrawal of the objections is respectfully requested.

Claim Rejections -35 U.S.C. § 112, first paragraph

In paragraph 5 of the Office Action, Claims 25-125 are rejected under 35 U.S.C. 112, first paragraph. The Examiner considers that these claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s). This rejection is respectfully traversed, on the basis that each of the limitations of Claims 25-125 referred to by the Examiner is supported by the disclosure of the specification as required by 35 U.S.C. §112, first paragraph, for the reasons stated more fully below, with respect to each limitation which the Examiner maintains is not disclosed.

"At least one milling surface"

Claims 25, 41, 52, 67, 82, 97 and 114 have been rejected under 35 U.S.C. §112, first paragraph with respect to the recitation of "at least one milling surface" which is present on the form cutter.

Claim 121 has been rejected under 35 U.S.C. §112, first paragraph with respect to the recitation of "at least one top milling surface".

Claim 53 has been rejected under 35 U.S.C. §112, first paragraph with respect to the recitation of "outwardly facing first and second milling surfaces."

"At least two milling surfaces . . . an end plate"

Claims 36, 77, 93, and 110 have been rejected under 35 U.S.C. §112, first paragraph with respect to the recitation of "at least two milling surfaces for simultaneously creating at least two predetermined surface contours on an end plate of one of the adjacent vertebral bodies."

Claim 68 has been rejected under 35 U.S.C. §112, first paragraph with respect to the recitation of "first and second milling surfaces"

Claim 98 has been rejected under 35 U.S.C. §112, first paragraph with respect to the recitation of "at least two milling surfaces"

These rejections are respectfully traversed. For the same reasons stated above with respect to the objection to the specification, Figs. 1-3 each disclose a form cutter 29 having two distinct milling surfaces which are the convex milling surface 42 and the concave milling surface having a raised edge 44 which surrounds it. (Specification, ¶¶25-27). In this illustrative embodiment of a form cutter according to the invention, the first convex milling surface 42 creates a cavity in the surface of a vertebral end plate and in combination with the second concave milling surface 44 forms a surrounding ridge in the

bone to hold the implant securely in place. The two milling surfaces thus simultaneously create at least two predetermined surface contours on an end plate of one of the adjacent vertebral bodies.

The specification, and more particularly, Fig. 2, thus clearly discloses a form cutter 29 having first 42 and second 44 milling surfaces, both of which face outwardly and upwardly from the housing 20 . (Specification, ¶27). The form cutter 29 has at least one top milling surface, because both milling surfaces 42 and 44 are on the top of form cutter 29.

The present invention is not limited with respect to the number of milling surfaces, and the specification clearly discloses one of ordinary skill in the art that the form cutter may be varied to provide a surface contour in the vertebral surface that corresponds to the contour of any desired endoprosthesis.

For example, one skilled in the art would appreciate that the representative surface contour 152, 154 in the vertebral surface as illustrated in Fig. 6 and more particularly in perspective in Fig.7 differs from the representative surface contour formed by the form cutter surfaces 42, 44 as illustrated in Figs. 1-3. In Figs. 6-7, the endoprosthesis does not have a peripheral ridge as formed by the form cutter profile illustrated in Figs 1-3. Instead, the endoprosthesis illustrated in Figs. 4-7 has a single convex surface 152, 154. Based on this disclosure, it is respectfully submitted that one skilled in the art would appreciate that the milling head used to create the cavity formed in the vertebral surface

for a representative endoprosthesis as shown in Figs. 6-7 can have a single convex milling surface.

Because the specification illustrates two embodiments of the invention, one of which includes a form cutter having two distinct milling surface contours, and the other which produces a single convex contour in the vertebral surface, it is respectfully submitted that one of ordinary skill in the art would appreciate from the specification and drawings that the invention includes a form cutter having a single milling surface, two milling surfaces, or a plurality of milling surfaces, which can be varied to suit the shape of an endoprosthesis.

For these reasons, withdrawal of the rejection of Claims 25, 36, 41, 52, 53, 67, 68, 77, 82, 93, 97, 98, 110, 114 and 121 is respectfully requested.

"At least one broad milling surface"

Claim 47 has been rejected under 35 U.S.C. §112, first paragraph with respect to the recitation of "at least one broad milling surface."

Claim 120 has been rejected under 35 U.S.C. §112, first paragraph with respect to the recitation of "a broad milling surface."

This rejection is respectfully traversed, for the same reasons stated immediately above with respect to Claims 25, 41, 52, 67, 82, 97 and 114. One skilled in the art would appreciate that the form cutter illustrated in Figs. 1-3, as well as the form cutter used to form the contour for the convex prosthesis illustrated in Figs. 4-7, have one or more

milling surfaces 42, 44 which are "broad" in diameter in comparison with the height of the form cutter 29 of the drill head portion 22. The form cutter profile is adapted to fit within the narrow space between adjacent vertebrae. (Specification, ¶29). Preferably, the maximum height of the cutter portion 22 of the drill head 20 is nine millimeters, which permits the drill head 20 of the present invention to fit in the narrow space between two opposing vertebral bodies in the cervical spine of a patient. (Specification, ¶29). In comparison with this restricted height profile, Figs. 1-3 illustrate embodiments in which the form cutter 29 has at least one broad milling surface, which is disclosed to be broad enough to mill a cavity in a vertebral end plate that extends substantially across the face of the vertebral end plate. (Figs 4,5, ¶¶42, 50-53).

Withdrawal of the rejection of Claims 47 and 120 is respectfully requested.

"A slot"

Claims 29, 86, and 103 have been rejected under 35 U.S.C. §112, first paragraph with respect to the recitation of "a slot." This rejection is respectfully traversed. The slot 46 disclosed in amended Fig. 2 extends through the surface of the upstanding wall 45 inside the housing near its proximal end. Drive shaft 54 extends through slot 46, and the wall 44 is an integral part of the housing 40 as shown in amended Fig. 2.

Withdrawal of the rejection of Claims 29, 86 and 103 is respectfully requested.

"Smooth surface"

Claims 37 (twice mentioned), 78, and 82 have been rejected under 35 U.S.C. §112, first paragraph with respect to the recitation of "a smooth surface." This rejection is respectfully traversed.

Claim 58 similarly has been rejected under 35 U.S.C. §112, first paragraph with respect to the recitation of "said bearing surface is smooth." This rejection is respectfully traversed.

In each of Figs. 1-3 illustrating embodiments according to the claimed invention, which are side views of the drill head 20 according to the invention, the surface 31 of the housing 20 opposite the cutter head surface 22, is shown to be flat and smooth. It is respectfully submitted that one of ordinary skill in the art, who is aware from the specification that the housing is adapted to be inserted into the narrow space between two adjacent vertebrae of the human spine, would appreciate that it is advantageous to provide a flat, smooth surface as illustrated in Figs. 1-3 to permit the housing to be inserted into the spine. (Specification, ¶¶29).

Withdrawal of the rejection of Claims 37, 58, 78 and 82 is respectfully requested.

"Said drive . . . end plates"

"Said milling surface . . . by said device"

Claim 48 has been rejected under 35 U.S.C. §112, first paragraph with respect to the recitation that "said drive means moves said form cutter in a plane generally parallel

to the predetermined surface contour to be formed in at least one of the end plates" of the adjacent vertebral bodies.

Claim 49 has been rejected under 35 U.S.C. §112, first paragraph, with respect to the recitation that "said milling surface of said form cutter is configured to be generally parallel to a receiving surface that is formed on one of the vertebral bodies by said device."

These rejections are respectfully traversed.

With respect to the recitation of Claim 48 that the milling surface is configured to be "generally parallel" to the predetermined surface contour to be formed in at least one of the end plates and "generally parallel to a receiving surface" that is formed on one of the vertebral bodies, applicants respectfully submit that this feature is shown by Figs. 1-3 as originally filed. When the rotary cutter 29 is driven in rotary motion by drive means 24, the movement of the rotating milling surfaces 42, 44, is in a plane that is generally parallel to a receiving surface in the end plates of a vertebral body 112, 114 as shown more particularly in Figs. 4-5. (Specification, ¶¶25-26, 50-53).

Further, Claim 15 as originally filed, which is part of the disclosure of the specification, recited that "the cutter is provided with a cutting edge so as to give the drill head the ability to cut in the direction of tool head entry into the space" between the vertebral bodies. This movement of the form cutter would also be in a plane parallel to the predetermined surface contour formed in the end plates of the vertebrae.

Withdrawal of the rejection of Claims 48 and 49 is respectfully requested.

"At least . . . vertebral bodies"

Claims 102 and 119 have been rejected under 35 U.S.C. §112, first paragraph with respect to the recitation of "at least . . . vertebral bodies"

The rejection of Claim 102 is respectfully traversed on the basis that Claim 102 does not contain the language cited by the Examiner.

Claim 119 recites that a milling surface of the form cutter is configured and oriented such that it is generally parallel to the surface having a predetermined contour created in the end plate of the "at least one of the adjacent vertebral bodies" when in use. The Examiner has rejected Claim 119 on the basis that the recitation "at least one of the adjacent vertebral bodies" is not supported by the specification.

This rejection is respectfully traversed. The drill head 20 shown in Figs. 1-3 is adapted to be inserted in the narrow space between adjacent vertebrae of the human spine (Specification, ¶¶11-13), and it is clear to one skilled in the art of spinal surgery that the form cutter 29 having a convex milling surface 42 and a concaval milling surface 44 are used to create a predetermined contour in the end plate of one of the adjacent vertebral bodies. (Specification, ¶¶25-26). In addition, as further shown in Figs. 4-6, the form cutter 29 is used to form a surface having a predetermined contour 212, 214, in both of the opposing adjacent vertebral bodies, in order to hold endoprosthesis 118 securely in

place between vertebrae 112, 114. (Specification, ¶¶45-46, 50-53). The endoprosthesis shown in Figs. 4-7 has opposing outer convex surfaces 152, 154 for engaging the mating surface milled by the form cutter milling surface 22. (Specification, ¶¶ 42, 45-46).

Applicants respectfully submit that the recitation "at least one of the adjacent vertebral bodies" in Claim 119 is supported by the specification, and that the rejection under 35 U.S.C. §112, first paragraph should be withdrawn.

"Width of the nucleus pulposus"

Claim 51 has been rejected under 35 U.S.C. §112, first paragraph with respect to the recitation of "the width of the nucleus pulposus." Applicants respectfully disagree with the Examiner's conclusion, but in order to advance prosecution, have cancelled Claim 51 without prejudice or disclaimer.

Method Claims

Claims 62-66 have been rejected under 35 U.S.C. §112, first paragraph with respect to the recitation of the steps of the claimed methods. This rejection is respectfully traversed.

The substitute specification (¶¶ 47-48) discloses that the present method may be used to form any predetermined shape in at least one of two adjacent vertebral bodies, to receive an endoprosthesis of any desired predetermined shape, and is not limited to the specific illustrative endoprostheses described in Figs. 4-7. More specifically, to implant the endoprosthesis assembly, information is obtained regarding the size, shape, and

nature of a patient's damaged natural spinal discs. If one or more of the patient's vertebral bodies also require replacement, information about those bodies is also obtained. Thereafter, one or more prosthetic disc units are constructed and preassembled in conformity with that information. (Specification, ¶48). Accordingly, it is clear to one skilled in the art that the milling surface width may be selected to provide any corresponding contour in the vertebral body, and that the disclosed method is performed with a device having a movable form cutter with a milling surface that has a width substantially the same as the width of the insert to be implanted between the adjacent vertebrae.

With respect to the steps of the method as claimed in Claims 62-66, it is respectfully submitted that the rejection is overcome by the incorporation of Figs. 4-7 and disclosure of the '296 patent. The substitute specification discloses (¶47) that the present invention includes a method of milling at least one of two adjacent vertebral bodies to form concaval-convex surfaces in the patient's spine, using drill head 20 as illustrated in Figs. 1-3. The concaval surfaces mate with corresponding surfaces of an endoprosthesis such as those described in Figs. 4-7. When a suitable endoprosthesis is made and the patient is properly prepared, the damaged natural spinal disc or discs and vertebral body or bodies are removed and the adjacent spinal bone surfaces are milled or otherwise formed to provide concave surfaces 212, 214, to receive the confronting convex surfaces 152, 154. (Specification, ¶50). The specification thus discloses to one of ordinary skill

in the art that the milling surface of the form cutter is contacted against at least one of the adjacent vertebrae to remove bone from the end plate of the vertebra that lies adjacent the disc space to form a surface of that vertebra having a contour that substantially matches the contour of a surface of the insert to be implanted and that substantially matches the contour of the milling surface.

In the method of Claims 62-66, as described in the substitute specification (¶52) with reference to Figs. 1-6, the desired surfaces of predetermined shape are formed on the inferior and superior surfaces of the opposing vertebral bodies using a drill head according to the invention as shown in Figs. 1-3. The desired surface of predetermined shape 212, 214 is formed by contacting the inferior or superior surface of opposing vertebral bodies 112, 114, with a form cutter 29 having at least one milling surface 42, 44 selected to create a predetermined surface contour in one of the adjacent vertebral bodies as the form cutter is moved by drive means 24, using one of a selection of predetermined form cutter sizes. (Specification, ¶52).

As further described in the substitute specification, thereafter the bone milling jig is removed and the concaval-convex elements 152, 154 identical in shape to the milled surfaces 212, 214 are inserted between the distracted milled vertebral bodies 112, 114. (Specification, ¶53).

It is respectfully submitted that the rejection of Claims 62-66 is overcome by the disclosure of the substitute specification, which describes the steps of the method as claimed in Claims 62-66 with specific reference to Figs. 1-6.

Withdrawal of the rejection of Claims 62-66 is respectfully requested.

Claim rejections - 35 U.S.C. § 112, second paragraph

In paragraph 7 of the Office Action, Claims 36, 50, 53, 54, 77, 93-96 98, 99 and 80, 81 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Examiner points out that in claims 80 and 81, "said at least two milling surfaces" lack antecedent basis. Applicants have now amended Claims 80 and 81 to recites "first and second milling surfaces," and antecedent basis for this recitation is found in Claim 68. Withdrawal of the rejections is respectfully requested.

The Examiner states that in claims 36, 50, 53, 54, 77, 93-96, 98 and 99, a broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. The Examiner considers that Claims 36, 50, 53, 54, 77, 93-96, 98 and 99 recite the broad recitation "at least one milling surface", and the claims also recite "at least two milling surfaces" which is the narrower statement of the range/limitation.

This rejection is traversed, on the basis that none of Claims 36, 50, 53, 54, 77, 93-96, 98 or 99 contains "the broad recitation 'at least one milling surface'" as the Examiner maintains. Each of these claims relates to a form cutter having at least two milling surfaces. Each of the rejected claims depends from a broader claim that recites "at least one milling surface" or "a milling surface" but this does not render the rejected dependent claims indefinite. Instead, the dependent claims, which require at least one additional milling surface, properly narrow the scope of the invention claimed in the independent claims. Contrary to the Examiner's position, none of the rejected dependent claims contains both a broader and a narrower definition with respect to the milling surface, and there is no basis for maintaining that these claims do not describe the invention with the definiteness required by 35 U.S.C. §112, second paragraph.

Withdrawal of the rejection of Claims 36, 50, 53, 54, 77, 93-96, 98 and 99 is respectfully requested.

Claim Rejections - 35 USC § 102

In paragraph 9 of the Office Action, Claims 1-3, 5-7 and 13-125 are rejected under 35 U.S.C. 102(b) as being anticipated by Scheicher (United States Patent 4,197,645). This rejection is respectfully traversed.

The Examiner states that in regard to claims 1-3, 5-7, and 13-24, Scheicher discloses, in Figs. 1-4 and 13-18, a milling apparatus or a device for preparing a space in human bone to receive an implant comprising head and bone drill comprising: a drill

head 11, a rotary form cutter 5, a drive means 40, elongate housing 3, said form cutter has a convex shape, a groove, and provided with a beveled gearing surface 37, the height of profile of the form cutter is approximately 9 mm, as disclosed in col. 17, line 56, said drive means having a pinion gear 39, and said cutter having a support shaft 8 which forms an angle approximately 96 degrees to the drive means. (angle approximately 96 degrees which generally could be 90 degrees).

The disclosure of Scheicher is limited to a drill head and bone drill that are used to drill into bone such as a jaw ridge 6 shown in the figures. The operation and configuration of the drill taught by Scheicher necessarily drills holes or cavities into a jawbone, but the drill is adapted to be inserted in the space between the upper teeth and the jawbone, which is much greater than the narrow space between human vertebrae. Furthermore, the drill disclosed in Scheicher has a diameter that necessarily must fit within the width of a human jawbone, which is necessarily much narrower than the end plate of a human vertebra.

The Examiner maintains that the statement of intended use of the device for preparing a space in a human spine to receive and insert between adjacent vertebral bodies does not impose any structural limitations on the claims patentably distinguishable over Scheicher. The Examiner considers that a recitation with respect to the manner in which a claimed article is intended to be employed does not differentiate the claimed article from the prior art article satisfying the claimed structural limitations.

Applicants respectfully disagree with this position. In the present claims, the recitation that the drill head has a profile of a height capable of being admitted into the space between two opposing intervertebral bodies is plainly a structural limitation, because it defines the height of the drill head profile, in terms of the distance between two vertebrae in the human spine. Similarly, the recitations with respect to the shape of the form cutter, which mills a surface in the end plate of a vertebral body having a surface contour which matches the shape of an endoprosthesis, is a structural limitation. The recitations that the milling surface is configured to substantially match in width and contour a surface of an interbody spinal insert is a structural limitation. The shape of the form cutter milling surface, which includes a convex surface, or at least two milling surfaces, is a structural limitation. Not one of these structural limitations is disclosed in Scheicher.

The Examiner has not pointed to any disclosure in Scheicher of a drill head for preparing the bone of two opposing intervertebral bodies comprising a form cutter with a profile of a height capable of being admitted into the space between two opposing intervertebral bodies (Claims 1); that the drill head has a profile capable of milling a space between adjacent vertebrae to receive an insert (Claims 25, 41, 47, 49, 62, 64, 65, 66, 67, 82, 97, 114, 120, 121); a drill head wherein the maximum height of the profile of the form cutter is approximately nine millimeters (Claim 20); a form cutter having at least one milling surface selected to create a surface contour in a vertebral body to receive an

insert between adjacent vertebral bodies (Claims 25, 28, 34, 41, 45, 67, 82, 91, 97, 114, 120, 121); a form cutter wherein at least one milling surface is convex (Claims 39, 45, 52, 80, 95, 112, 117, 123); a form cutter having a width selected to match the width of an insert received between adjacent vertebral bodies (Claims 41, 47, 49, 62, 65, 114, 120, 121); a form cutter having at least one broad milling surface (Claims 47, 120); or a form cutter having at least at two milling surfaces for simultaneously creating at least two predetermined surface contours on an end plate of a vertebral body (Claims 36, 39, 40, 77, 80, 81, 93, 95, 96, 98, 110, 112, 113), of a form cutter having first and second outwardly facing milling surfaces (Claims 50, 53, 54, 63, 67, 68, 80, 81, 102).

In the absence of disclosure of these limitations of the independent and dependent claims, the anticipation rejection of Claims 1-3, 5-7 and 13-125 is improper and should be withdrawn.

With respect to the Examiner's assertion that the profile of the dental cutters 5 in Scheicher is approximately 9 mm, although Scheicher teaches that the distances between the rotational axes 9 of the cutters 5 are within a range of 2.5 mm to 10 mm, these distances have no direct relationship to the profile of the cutters 5 in the drilling direction (*e.g.*, parallel to distance B shown in Figure 1). Furthermore, Claim 20 requires that the profile of the rotary form cutter contained within the housing be not more than approximately 9 mm in height. Scheicher does not appear to disclose this feature since the profile of the housing including drill head 4 along with cutters 5 could not be 9 mm or

less. Even assuming that the distance A shown in Figure 1 is the minimum of 2.5 mm, the relative scale of the distance B plus the height of the drill head casing 11 would not be 9 mm or less. The Examiner is respectfully requested to point to any teaching in Scheicher of a drill head having a profile that could be inserted into the space between two human vertebrae, or a rotary form cutter having a broad surface, or a rotary form cutter that could be used to mill the end plate of a vertebra, to form a surface contour adapted to receive a spinal endoprosthesis. Applicants submit that a dental drill, which is the only teaching of Scheicher, cannot anticipate any of the present claims, because there is no teaching in the reference of a drill head or form cutter having a structural configuration that could be used to perform a milling operation on the end plate of a vertebra, to form a surface contour with the structure recited in the present claims.

The Examiner is respectfully requested to point out the disclosure of Scheicher which anticipates each of Claims 25-61 and 67-125, with respect to the numerous structural limitations listed above. It is necessary for the Examiner to cite disclosure of each claim limitation in a single reference in order to pose a proper anticipation rejection. Applicants submit that none of the structural limitations listed above is disclosed in Scheicher.

Moreover, although the Examiner suggests that Scheicher teaches a cutter having a support shaft 8 which forms an angle which could be 90 degrees to the drive means, the reference is devoid of any teaching that the angle between the support shaft of the form

cutter and the drive shaft is not 90 degrees, but instead is approximately 96 degrees, as recited in Claim 22. Because the reference fails to disclose this limitation of the present claims, the anticipation rejection is improper and should be withdrawn.

With respect to method Claims 62-66, the Examiner states only that the Scheicher device is capable to perform the steps as claimed. Applicants submit that Scheicher is devoid of any mention of any method for preparing the disc space between adjacent vertebrae of a human spine to receive an insert therebetween, and indeed, is devoid of any mention of human vertebrae, a spinal endoprosthesis, a drill head having a structural configuration that permits the milling surface to be inserted into the space between two vertebrae, the contour of a spinal endoprosthesis, the use of a form cutter including first and second outwardly facing milling surfaces, determining the width of a spinal implant and selecting a form cutter with a milling surface that matches the measured width, or the steps of milling adjacent vertebrae in any fashion, much less to contain an insert between two adjacent vertebrae.

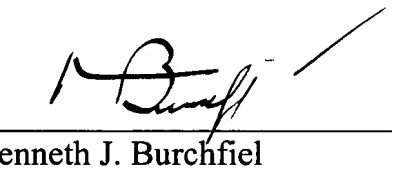
Applicants submit that the anticipation rejection posed by the Examiner is without basis, because the reference contains no disclosure of any of the method steps recited above. Applicants disagree with the Examiner that the dental drill disclosed by Scheicher could be used to perform spinal surgery, or to mill vertebral bodies to receive spinal implants. This assertion by the Examiner, however, is beside the point. The reference

does not disclose any such method. Withdrawal of the rejection of claims 62-66 is respectfully requested.

Reconsideration of the rejections of Claims 1-3, 5-7 and 13-125, and early allowance of all pending claims, is requested in view of the amendments and arguments made herein. All pending claims are now believed to be allowable, but if any question with respect to patentability remains, the applicants respectfully request a personal or telephone interview with the Examiner. In this case, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



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APPENDIX

VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE SPECIFICATION:

Please substitute the attached amended specification.

IN THE CLAIMS:

Claim 51 is canceled.

Please amend Claims 80, 81, and 121 as follows:

80. (amended) The device of claim 68, wherein at least one of said [at least two] first and second milling surfaces of said form is convex.

81. (amended) The device of claim 68, wherein at least one of said [at least two] first and second milling surfaces of said form cutter is tapered outwardly from a front surface of said form cutter.

121. (amended) A form cutter for preparing a space between adjacent vertebral bodies to receive an insert, said form cutter having:

(a) at least one top milling surface for removing bone;

(b) [A] a bottom surface opposite said at least one top milling surface adapted to mount on a device capable of moving said form cutter;

(c) said at least one top milling surface of said moving form cutter being capable of removing bone from an end plate of at least one of said adjacent vertebral bodies to create at least one surface in said end plate having a predetermined contour;

(d) said at least one top milling surface having a width selected to substantially

match the overall width of said insert to be received between said adjacent vertebral bodies; and

(e) said form cutter having a leading edge configured to cut into the vertebral body as said form cutter is inserted into the spine.

#44

MILLING HEAD FOR USE IN PLACING A VERTEBRAL BODY DISC DEVICE

should be deleted

[01] This is a Continuation of U.S. Patent Application No. 08/944,234 filed October 6, 1997.

BACKGROUND OF THE INVENTION

[02] This invention relates generally to drill heads and more particularly to drill heads for use in placing a vertebral body disc device.

[03] The herniation of a spinal disc and the often resultant symptoms of intractable pain, weakness, sensory loss, incontinence and progressive arthritis are among the most common of debilitating processes affecting mankind. If a patient's condition does not improve after conservative treatment, and if clear physical evidence of nerve root or spinal cord compression is apparent, and if correlating radiographic studies (i.e., MRI or CT imaging or myelography) confirm the condition, surgical removal of the herniated disc may be indicated. The process of discectomy -- as the name implies -- involves the simple removal of the disc without attempt to replace or repair the malfunctioning unit. In the United States in 1985, over 250,000 such operations were performed in the lumbar spine and in the cervical spine.

[04] Statistics suggest that present surgical techniques are likely to result in short-term relief, but will not prevent the progressive deterioration of the patient's condition in the long run. Through better pre-operative procedures and diagnostic studies, long-term patient results have improved somewhat. But it has become clear that unless the removed disc is replaced or the spine is otherwise properly supported, further degeneration of the patient's condition will almost certainly occur.

[05] In the mid-1950's and 60's, Cloward and Smith & Robinson popularized anterior surgical approaches to the cervical spine for the treatment of cervical degenerative disc disease and related disorders of the vertebrae, spinal cord and nerve root; these surgeries involved disc removal followed by interbody fusion with a bone graft. It was noted by Robinson (Robinson, R. A.: The Results of Anterior Interbody

Fusion of the Cervical Spine, J. Bone Joint Surg., 440A: 1569 1586, 1962) that after surgical fusion, osteophyte (bone spur) reabsorption at the fused segment might take place. However, it has become increasingly apparent that unfused vertebral segments at the levels above and below the fused segment degenerate at accelerated rates as a direct result of this fusion. This has led some surgeons to perform discectomy alone, without fusion, by a posterior approach in the neck of some patients. However, as has occurred in surgeries involving the lower back where discectomy without fusion is more common as the initial treatment for disc herniation syndromes, progressive degeneration at the level of disc excision is the rule rather than the exception. Premature degenerative disc disease at the level above and below the excised disc can and does occur.

[06] Spine surgery occasionally involves fusion of the spine segments. In addition to the problems created by disc herniation, traumatic, malignant, infectious and degenerative syndromes of the spine can be treated by fusion. Other procedures can include bone grafts and heavy duty metallic rods, hooks, plates and screws being appended to the patient's anatomy; often they are rigidly and internally fixed. None provide for a patient's return to near-normal functioning. Though these procedures may solve a short-term problem, they can cause other, longer term, problems.

[07] A number of attempts have been made to solve some of the problems described above by providing a patient with spinal disc prostheses, or artificial discs of one sort or another. For example, Steffee, U.S. Patent 5,031,437, describes a spinal disc prosthesis having upper and lower rigid flat plates and a flat elastomeric core sandwiched between the plates. Frey et al., U.S. Patents 4,917,704 and 4,955,908, disclose vertebral prostheses, but the prostheses are described as solid bodies.

[08] U.S. Patents 4,911,718 and 5,171,281 disclose resilient disc spacers, but no inter-connective or containing planes or like elements are suggested, and sealing the entire unit is not taught.

[09] U.S. Patent No. 5,674,296, incorporated herein by reference, provides a vertebral disc endoprosthesis which addresses these shortcomings of the prior art. The endoprosthesis comprises a resilient body formed of a material varying in stiffness

from a relatively stiff exterior portion to a relatively supple central portion. A concaval-convex means at least partly surrounds that resilient body so as to retain the resilient body between adjacent vertebral bodies of a patient's spine. If medical considerations so indicate, several disc endoprosthesis can be combined with one or more endoprosthetic vertebral bodies in an entire assembly.

[10] The endoprosthesis has a resilient body formed of one or more materials which may vary in stiffness from a relatively stiff exterior annular gasket portion to a relatively supple central nucleus portion. Concaval-convex elements at least partly surround that nucleus portion so as to retain the nucleus portion and gasket between adjacent vertebral bodies in a patient's spine. Assemblies of endoprosthetic discs, endoprosthetic vertebral bodies, and endoprosthetic longitudinal ligaments may be constructed. To implant this endoprosthesis assembly, information is obtained regarding the size, shape, and nature of a patient's damaged spine. Thereafter, one or more prosthetic vertebral bodies and disc units are constructed in conformity with that information. Finally, the completed and conformed vertebral body and disc assembly is implanted in the patient's spine.

[11] In order to place the above endoprosthesis in a patient's spine, the bone of the two opposing vertebral bodies must be prepared in such a manner so as to accept the concaval-convex shape of endoprosthesis. However, currently available drill heads are not always capable of being fit into the narrow space between two opposing vertebral bodies. Further, the narrow space between two opposing vertebral bodies cannot always be expanded to allow admittance of currently available drill heads.

[12] Thus, it is an object of the instant invention to provide a drill head which can fit within the narrow space between two opposing vertebral bodies.

[13] It is another object of the instant invention to provide a drill head which can prepare the bone of the two opposing vertebral bodies to accept the concaval-convex shape of an endoprosthesis.

[14] These and other objects and advantages of the instant invention will be apparent from the following description and drawings.

SUMMARY OF THE INVENTION

[15] The instant invention overcomes the deficiencies of the prior art devices by providing a drill head with a narrow profile which can fit in the space between two opposing vertebral bodies.

[16] The drill head of the instant invention is provided with a form cutter having a convex shape so as to prepare the bone of vertebral bodies to accept the concaval-convex shape of an endoprosthesis.

BRIEF DESCRIPTION OF THE DRAWINGS

[17] Figure 1 is a side view of one embodiment of the instant invention.

[18] Figure 2 is a cross-sectional view of the embodiment of Figure 1.

[19] Figure 3 is a partial cross-sectional view of an alternate embodiment of the instant invention.

[20] FIG. 4 is a fragmentary vertical view of a portion of a human spine in which is installed a vertebral disc endoprosthesis.

[21] FIG. 5 is a fragmentary side elevational view similar to FIG. 4 showing the elements of a patient's spine and having a vertebral disc endoprosthesis installed therein.

[22] FIG. 6 is a sectional view taken substantially in the plane of line 3--3 in FIG. 4.

[23] FIG. 7 is an exploded view of the vertebral disc endoprosthesis.

DETAILED DESCRIPTION OF THE INVENTION

[24] While the invention will be described in connection with a preferred embodiment and procedure, it will be understood that it is not intended to limit the invention to this embodiment or procedure. On the contrary, it is intended to cover all alternatives, modifications, and equivalents as may be included within the spirit and scope of the invention as defined by the appended claims.

[25] One embodiment of the drill head of the present invention is depicted in Figures 1 and 2. The drill head 20 generally comprises a form cutter portion 22, drive means 24, and attachment means 26. In accordance with the invention, the form cutter

profile imparts a shape to the bone of the vertebral bodies which mates with the predetermined endoprosthesis surface shape.

[26] As seen in Figure 2, the drill head 20 includes a form cutter 29 carried by a housing 31 having an upstanding wall 35 and a shaft support 37 for supporting the form cutter 29. The housing 31 further includes an elongated shaft portion 40 which houses the drive shaft discussed below. To provide a drill head which can prepare the bone of the two opposing vertebral bodies to accept the concaval-convex shape of an endoprosthesis, the illustrated form cutter 29 has a convex milling surface 42. This convex surface 42 of the form cutter 29 functions to provide the bone of a vertebral body with a mating shape complementary to the concaval-convex shape of the endoprosthesis which is the subject of U.S. Patent No. 5,674,296.

[27] The form cutter 29 further includes an outwardly and upwardly extending edge 44 about its perimeter. In addition, the undersurface 47 of the form cutter 29 may be provided with a beveled gearing surface 49. Alternately, the beveled gearing surface 49 may be provided about the undersurface of the upstanding edge.

[28] The form cutter 29 is provided with a shaft 51 extending perpendicularly from its undersurface. The form cutter 29 is supported within the housing 31 by the cooperation between the shaft 51 and the shaft support 37. This arrangement permits the form cutter 29 to be removed from the housing 31 by separating the shaft 51 from the shaft support 37. Thus, when the cutter dulls, it can be replaced with a new cutter to ensure accurate and effective performance of the drill head.

[29] In order to provide a drill head which can fit within the narrow space between two opposing vertebral bodies in accordance with the invention, the maximum height of the illustrated form of the cutter portion 22 of the drill head 20 is nine millimeters, Providing the bevel gearing surface 49 on the form cutter 29 allows the drill head 20 to be manufactured with such a narrow profile. This arrangement eliminates the need for a separate gear and form cutter which would likely add to the height of the drill head. Because of its profile, the drill head 20 of the present invention can fit in the narrow space between two opposing vertebral bodies in the cervical spine of a patient.

[30] To provide a driving force to the form cutter 29, the drill head 20 is provided with drive means 24. As shown in Figure 2, the drive means 24 comprises a drive shaft 54 operatively coupled at its distal end to the form cutter 29 and at its proximal end to a drive source 61. The distal end of the drive shaft 54 is supported by a journal 56 within the housing and is provided with a pinion gear 59. As mentioned above, the undersurface 47 of the form cutter 29 is provided with a beveled gearing surface 49. When the drive shaft 54 rotates, the pinion gear 59 also rotates and cooperates with the beveled gearing surface 49 of the form cutter 29, thereby causing the form cutter 29 to rotate about the shaft 51.

[31] The proximal end of the drive shaft 54 is operatively coupled to a suitable drive source 61 by coupling means 63. Although a drive source is not shown in the embodiment of Figures 1 and 2, it should be understood that the drive source shown by Figure 3 or its functional equivalent could be employed. The illustrated drive source 61 comprises a suitable motor 65 having mating coupling means 69. The motor 65 imparts a driving force to the drive shaft 54 via the mating of the coupling means 63, 69. The drive shaft 54 extends through slot 46 provided in a second upstanding wall 45 at the proximal end of shaft 40.

[32] As shown in Figure 2, the form cutter 29 is not necessarily oriented at a right angle with respect to the drive shaft 54. In the illustrated device, the angle between the support shaft 51 of the form cutter 29 and the drive shaft 54 is approximately 96° to provide a designed orientation to the vertebral bone surface being milled.

[33] The housing 31, which houses the form cutter 29 and the drive shaft 54, is provided at its proximal end with an attachment means 71. The attachment means 71 allows the drive source to be attached to the drill head 20 of the present invention. In the embodiment of Figure 2, the drive source is attached to the drill head 20 via threads 73. However, alternate equivalent attaching means could be employed to attach the drive source to the drill head 20. The housing 31 is also provided with a ring 75 about its circumference.

[34] An alternate embodiment of the drive means 24 used in the drill head is shown in Figure 3. Rather than being driven by a gear and pinion mechanism, the drill head

20 is driven by a drive belt 78. To accommodate the belt driving arrangement, the form cutter 29 is provided with a groove 80 about its perimeter rather than being provided with a beveled gearing surface. The groove 80 interacts with the drive belt 78 to provide a driving force to the form cutter 29. This alternate driving arrangement enables the drill head 20 to be manufactured with a narrow profile.

[35] As mentioned above, in this embodiment of the invention, the drive means 24 comprises a drive belt 78 which is operatively coupled to the form cutter 29 at the distal end of the drill head 20. The belt 78 loops around the form cutter 29 within the groove 80. At the proximal end of the drill head 20, a drive shaft 82 is provided which is operatively coupled to a suitable drive source 61. The drive shaft 82 is provided with a pulley 85 about which the belt 78 is looped. At one end, the drive shaft 82 is supported by the housing 31 with suitable means such as a bearing or bushing 87. At its opposite end, the drive shaft 82 is provided with a coupling means 63 for coupling to a suitable drive source 61. When the drive source 61 acts upon the drive shaft 82 and causes it to rotate, the pulley 85 is caused to rotate, thereby driving the belt 78 and causing the form cutter 29 to rotate.

[36] To accommodate the driving means arrangement of this alternate embodiment, the housing 31 is provided with a perpendicular extension 90 at the proximal end of the drill head 20. The extension 90 is provided with the attachment means 71 for attaching the drill head 20 to a suitable drive source 61. It is within the extension 90 that the drive shaft 82 is coupled to the drive source 61. The housing extension 90 is further provided with an intermediate support member 92 for providing additional support to the drive shaft 82.

[37] As mentioned above, the drill head 20 generally comprises a form cutter portion 22, drive means 24, and attachment means 26. In accordance with the invention, the form cutter profile imparts a shape to the bone of the vertebral bodies which mates with the predetermined endoprosthesis surface shape.

[38] As also stated above, as seen in Figure 2, the drill head 20 includes a form cutter 29 carried by a housing 31 having an upstanding wall 35 and a shaft support 37 for supporting the form cutter 29. The housing 31 further includes an elongated shaft

portion 40 which houses the drive shaft discussed below. To provide a drill head which can prepare the bone of the two opposing vertebral bodies to accept the concaval-convex shape of an endoprosthesis, the illustrated form cutter 29 has a convex milling surface 42. This convex surface 42 of the form cutter 29 functions to provide the bone of a vertebral body with a mating shape complementary to the concaval-convex shape of the endoprosthesis which is the subject of U.S. Patent No. 5,674,296. The form cutter 29 further includes an outwardly and upwardly extending edge 44 about its perimeter.

[39] As further explained above, in order to provide a drill head which can fit within the narrow space between two opposing vertebral bodies in accordance with the invention, the maximum height of the illustrated form of the cutter portion 22 of the drill head 20 is nine millimeters. Because of its profile, the drill head 20 of the present invention can fit in the narrow space between two opposing vertebral bodies in the cervical spine of a patient.

[40] The concave mating shape formed in the bone of a vertebral body by convex surface 42 of the form cutter 29 that is complementary to the concaval-convex shape of the endoprosthesis is further illustrated in Figs. 4 to 6.

[41] Turning more specifically to FIGS. 4-6, a portion of a human spine 110 is shown. The illustrated spine 110 has been subjected to a discectomy surgical process. To discourage degeneration of or damage to the natural vertebral bodies 112 and 114 and their respective facet joints, a vertebral disc endoprosthesis 118 is affixed between the adjacent natural vertebral bodies 112 and 114. This vertebral disc endoprosthesis 118 comprises a resilient disc body 120 having a relatively stiff annular gasket exterior portion 122 and a relatively supple nuclear central portion 124.

[42] In the illustrative vertebral disc endoprosthesis described in detail in United States Patent 5,674,296, concaval-convex means 130 surround the resilient body 120 to retain the resilient body 120 between the adjacent natural vertebral bodies 112, 114 in a patient's spine 110. To this end, as shown in FIG. 6, the concaval-convex means 130 comprise two generally L-shaped supports 132 and 134. The supports 132, 134 each have confronting first concaval-convex legs 142, 144, each leg being of

relatively constant cross-sectional thickness. Each leg 142, 144 has an outer convex surface 152, 154 for engaging the adjacent bone of the natural vertebral bodies 112, 114. Corresponding inner concave surfaces 162, 164 in confronting array retain the resilient body 120 in its illustrated compressive force shock-absorbing position.

[43] As further described in United States Patent 5,674,296, supports 132 and 134 can undergo principle movement away from one another, but only limited secondary translational, rotational and distractional motion will occur. Each support 132, 134 has a second wing or leg 172, 174 extending generally perpendicularly to the first legs 142, 144 respectively, and adapted for affixation to the adjacent bone structure. This affixation is effectively accomplished by cannulated screw devices 182, 184, each of which comprises a screw 192, 194; and a screw anchor 202, 204 adapted to threadably receive the screw extends radially into and seats within the bone structure 112, 114 as especially shown in FIG. 6.

[44] As also described in United States Patent 5,674,296, to discourage and prohibit migration of fluids between the endoprosthesis 118 and adjacent parts of the anatomy, a seal member 210 is attached to the supports 132, 134 so as to surround the resilient body 120 comprised of the gasket 122 and nucleus 124. The seal member 210 comprises a flexible sheet material having a multiplicity of pores. Preferably, the pores are from about 5 microns to about 60 microns in size. Flexible, strong polymer sheet materials from which this seal is formed are described in United States Patent 5,674,296. Known sealing material can be applied to the flexible sheet material so as to render the flexible sheet material substantially impervious to the passage of any fluid. A watertight seal is perfected when the seal 210 is glued or otherwise affixed to the legs 142, 144 and mediate portions of the legs 172, 174 as suggested in FIGS. 3-6.

[45] FIG. 7 is an exploded view of a representative vertebral disc endoprosthesis, in which the outer convex surface 152 of concaval-convex means 132 for engaging the adjacent bone of the natural vertebral body and the inner concave surface 164 of concaval-convex means 134 confronting resilient body 120 are shown. In this embodiment of the endoprosthesis 118, the resilient body 120 is surrounded by a gasket 122 and a seal member 210.

[46] As illustrated in Figs. 4-6, It is necessary to install the endoprosthesis so as to accurately mate the outer convex surface 152, 154 of the endoprosthesis 118 with an adjacent specifically formed bone surface 212, 214 on the ends of vertebrae 112, 114.

[47] The present invention includes a method of milling at least one of two adjacent vertebral bodies to form concaval-convex surfaces in the patient's spine, using drill head 20 as illustrated in Figs. 1-3. The concaval surfaces mate with corresponding surfaces of an endoprosthesis such as those described in Figs. 4-6. However, the present method may be used to form any predetermined shape in at least one of two adjacent vertebral bodies, to receive an endoprosthesis of any desired predetermined shape, and is not limited to the specific illustrative endoprostheses described in Figs. 4-6.

[48] To implant the endoprosthesis assembly, information is obtained regarding the size, shape, and nature of a patient's damaged natural spinal discs. If one or more of the patient's vertebral bodies also require replacement, information about those bodies is also obtained. Thereafter, one or more prosthetic disc units are constructed and preassembled in conformity with that information. Finally, the completed and conformed prosthetic disc unit is implanted in the patient's spine.

[49] More specifically, in one embodiment of the method of preparing the disc space between adjacent vertebrae of a human spine to receive an insert therebetween, a surgeon or medical technician develops information about the size, shape and nature of a patient's damaged vertebral body or bodies from radiographs, CT and/or MRI scans, noting specifically the anterior-posterior and lateral dimensions of the end plate of each involved vertebral body and the vertical height of the anterior aspect of each involved vertebral and/or proximate vertebral body and vertical height of the mid portion of involved and proximate relatively normal intervertebral disc spaces. This information is transmitted by telephone, computer datalink or documentary transport to a specialized laboratory. That laboratory constructs one or more prosthetic assemblies including at least one prosthetic disc unit 118 as shown in Figs. 4-6, which comprises, in turn, the concaval-convex elements 130; the resilient body 120

interposed between the concaval-convex elements; and the seal unit 210 secured around the interior legs and resilient body.

[50] When the unit or units have been received and the patient properly prepared, the damaged natural spinal disc or discs and vertebral body or bodies are removed and the adjacent spinal bone surfaces are milled or otherwise formed to provide concave surfaces 212, 214, to receive the confronting convex surfaces 152, 154.

[51] In order to accurately locate the concaval-convex surfaces in the patient's spine, it is advantageous to precisely locate and form holes 482, 484 (FIG. 6) in the bone structure using a measuring instrument centered in the evacuated natural intravertebral disc space. These holes are then tapped to form female threads therein. When the threads have been formed, the anchors 202, 204 are implanted in the respective tapped holes, thereby creating an imaginary platform of reference points located precisely with respect to the patient's spine.

[52] After the holes have been formed and the anchors 202, 204 implanted, a bone surface milling jig (not shown) is affixed to the anchors 202, 204 and the desired surfaces of predetermined shape are formed on the inferior and superior surfaces of the opposing vertebral bodies using a drill head according to the invention as shown in Figs. 1-3. The desired surface of predetermined shape 212, 214 is formed by contacting the inferior or superior surface of opposing vertebral bodies 112, 114, with a form cutter 22 having at least one milling surface 42, 44 selected to create a predetermined surface contour in one of the adjacent vertebral bodies as the form cutter is moved by drive means 24, using one of a selection of predetermined form cutter sizes.

[53] Thereafter, the bone milling jig is removed and the concaval-convex elements 152, 154 identical in shape to the milled surfaces 212, 214 are inserted between the distracted milled vertebral bodies 112, 114. The distraction device is then moved. The concaval-convex structures are then attached by the same anchors 202, 204 to the bone, thus insuring a precise and stable mate between the bone surfaces and the convex surfaces 152, 154.

ABSTRACT OF THE DISCLOSURE

A drill head for preparing the bone of two opposing vertebral bodies to accept the concaval-convex shape of an endoprosthesis includes a form cutter having at least one predetermined milling surface, drive means, and a housing. The form cutter has a profile allowing the drill head to fit in the narrow space between two opposing vertebral bodies in the cervical spine of a patient. The drill head is used in a method for preparing the disc space between adjacent vertebrae of a human spine to receive an endoprosthesis therebetween, the method being performed by contacting at least one vertebral body with a movable form cutter having a milling surface that has a width substantially the same as the width of the endoprosthesis to be implanted between the adjacent vertebrae.